

What is Claimed:

1               1. A system for deployment of a stent inside of a biocompatible  
2 graft cover in a distal deployment location in a body lumen from a proximal access  
3 location outside the body lumen, said lumen defining an interior space therein, the  
4 delivery system comprising:

5               a stent sheath having a distal end located upstream relative to a fluid  
6 flow direction in said body lumen;

7               a compressed stent underlying the stent sheath, the stent having a  
8 proximal end housed within said stent sheath and a distal end; and

9               a compressed biocompatible graft cover overlying the stent sheath along  
10 the length of the stent and releasably retained in a compressed state surrounding said  
11 sheath, said graft having a distal end attached to said stent at or proximal said stent  
12 distal end and an outer surface exposed to the interior space of said lumen during  
13 deployment.

1               2. The system of claim 1 in which the stent distal end extends  
2 distally past the stent sheath distal end, and the stent distal end is secured in a  
3 compressed form by a crochet.

1               3. The system of claim 1 wherein the stent distal end extends  
2 distally past the stent sheath distal end, and said system further comprises a tip  
3 comprising a tip sheath overlying the stent distal end.

1                  4.        The system of claim 3 further comprising an inner core attached  
2 to said tip and extending axially through said stent.

1                  5.        The system of claim 4 wherein said inner core and said tip have a  
2 guidewire lumen therein adapted for receiving a guidewire.

1                  6.        The system of claim 4 further comprising a pusher underlying  
2 said stent sheath proximal to the stent and wherein said inner core is attached to and  
3 extends distally from said pusher.

1                  7.        The system of claim 4 further comprising a pusher underlying  
2 said stent sheath proximal to the stent, said pusher comprising an inner lumen  
3 extending axially therethrough within which said inner core is axially mounted.

1                  8.        The system of claim 7 wherein the pusher distal end is rounded.

1                  9.        The system of claim 7 wherein the inner core is tensionally  
2 biased.

1                  10.      The system of claim 1 wherein the stent delivery system further  
2 comprises a temporary, protective wrapper over said biocompatible graft, said wrapper  
3 adapted to be removed prior to insertion of said system into said body lumen.

1                  11.      The system of claim 1 wherein the compressed biocompatible  
2 graft further comprises a proximal end attached to the stent sheath by a releasable  
3 attachment adapted to be released during deployment of the stent.

1                  12.      The system of claim 11 wherein the releasable attachment is a  
2 suture.

1               13.     The system of claim 12 wherein the suture is secured with a slip-  
2 knot adapted to be untied during stent deployment.

1               14.     The system of claim 12 further comprising a tip comprising a tip  
2 sheath overlying the stent distal end, a pusher underlying said stent sheath proximal to  
3 the stent and comprising an inner lumen extending axially therethrough, and an inner  
4 core attached to said tip and extending axially through said stent and said pusher inner  
5 lumen.

1               15.     The system of claim 14 wherein the pusher further comprises a  
2 cutter adapted for severing the suture upon movement of the pusher relative to the stent  
3 sheath.

1               16.     The system of claim 15 wherein the cutter is a sharpened  
2 hypotube.

1               17.     The system of claim 15 wherein:

2               the stent sheath has a circumference having therein a suture connection  
3 point and a first and second through-hole, said through-holes radially opposite one  
4 another;

5               the pusher has a distal end having a window therein, said window  
6 aligned with the stent sheath through-holes and having a cutter proximally positioned  
7 therein; and

8               the suture has opposite ends attached to said suture connection point and  
9 an intermediate section threaded through said graft in one or more locations, through  
10 said sheath through-holes, and through said pusher window.

1               18. The system of claim 17 in which the suture has a first and a  
2 second end, wherein the first end is anchored to the suture connection point and the  
3 suture extends distally along the stent sheath from the suture connection point, pierces  
4 the graft one or more times, returns proximally along the stent sheath, enters the stent  
5 sheath radially through the first through-hole, extends through the pusher window, exits  
6 the stent sheath through the second through-hole, extends distally along the stent  
7 sheath, pierces the graft one or more times, extends semi-circumferentially around the  
8 stent sheath to the suture connection point, where the suture second end is anchored to  
9 the suture connection point or to the suture first end.

1               19. The system of claim 17 wherein the suture connection point  
2 comprises a pair of tie-holes in said stent sheath.

1               20. The system of claim 11 wherein the releasable attachment is a  
2 crochet weave around the proximal end of the graft.

1               21. The system of claim 11 wherein the releasable attachment  
2 comprises a bead of biocompatible adhesive between the graft and the stent sheath, said  
3 adhesive adapted to soften or dissolve when exposed to blood for a predetermined  
4 amount of time.

1               22. The system of claim 11 wherein the stent sheath comprises a slot  
2 therein adapted to receive a portion of the graft and the pusher comprises an indented  
3 portion thereof, the releasable attachment comprising a portion of the graft disposed  
4 within said slot and pinched between said pusher and said stent sheath in a first position  
5 of said stent sheath relative to said pusher, said graft portion in said slot adapted to be  
6 released in a second position of said stent sheath relative to said pusher in which said  
7 indented portion of said pusher aligns with said slot in said stent sheath.

1                   23. The system of claim 22 wherein the graft comprises a tab, a  
2 portion of said tab being adapted to be the portion of the graft disposed within said slot.

1                   24. A method for endoluminally deploying a stent and overlying  
2 biocompatible graft cover in a distal deployment location inside a lumen from a  
3 proximal access location, said lumen defining an interior space therein, the method  
4 comprising the steps of:

5                   a) compressing the stent and graft and loading the compressed stent  
6 and compressed graft into a delivery system, the delivery system comprising a stent  
7 sheath having a distal end located upstream relative to a flow direction of intraluminal  
8 fluid in the lumen, the compressed stent underlying the stent sheath and having a distal  
9 end, and the compressed graft overlying the stent sheath along the length of the stent  
10 and releasably retained in a compressed state surrounding said sheath, said graft having  
11 a distal end attached to the stent at or proximal the stent distal end and an outer surface  
12 exposed to the interior space of said lumen during deployment;

13                  b) inserting the delivery system into a lumen and navigating said  
14 delivery system through said lumen so that said stent is at a desired deployment  
15 location;

16                  c) proximally displacing the stent sheath relative to the distal end of  
17 the stent, allowing the stent distal end to expand, and allowing endoluminal fluid to  
18 flow between the stent sheath and the graft so that the graft becomes radially distanced  
19 from the stent sheath; and

20                  d) completing deployment of the stent so that it biases the graft  
21 against the body lumen.

1           25. The method of claim 24 wherein the delivery system further  
2 comprises a temporary, protective wrapper over said biocompatible graft cover and in  
3 which the method further comprises prior to step (b) removing said temporary,  
4 protective wrapper.

1           26. The method of claim 24 wherein the stent distal end is spaced  
2 distally from the stent sheath distal end stent and the delivery system further comprises  
3 a tip comprising a tip sheath overlying the stent distal end and attached to an inner core  
4 extending axially through the stent, and wherein step (c) comprises first releasing the  
5 stent distal end from the tip sheath by displacing the inner core distally relative to the  
6 stent sheath, and then retracting said stent sheath to deploy said stent.

1           27. The method of claim 26 wherein the delivery system further  
2 comprises a pusher underlying the stent sheath proximal to the stent, said pusher having  
3 a distal end attached to said inner core, wherein moving the inner core distally relative  
4 to the stent sheath to release the stent distal end from the tip sheath in step (c)  
5 comprises a single, continuous, proximal retraction of the stent sheath that also  
6 displaces said pusher distally relative to said stent sheath to deploy said stent.

1           28. The method of claim 26 wherein the delivery system further  
2 comprises a pusher underlying the stent sheath proximal to the stent, said pusher having  
3 an inner lumen axially therethrough within which the inner core is axially mounted,  
4 wherein step (c) comprises first advancing the inner core distally relative to the stent  
5 sheath and pusher to release the stent distal end from the tip sheath, and then retracting  
6 said stent sheath to deploy said stent.

1           29. The method of claim 24 wherein the biocompatible graft further  
2 comprises a proximal end attached to the stent sheath by a releasable attachment, and

3       wherein the method further comprises in step (c) releasing the releasable attachment  
4       prior to the endoluminal fluid flowing between the stent sheath and the graft.

1           30.      The method of claim 29 wherein the releasable attachment is a  
2       crochet weave wrapped around said graft and comprising a continuous filament having  
3       a proximal end trailing outside said lumen, and in which step (c) further comprises  
4       pulling said proximal end and untying said crochet weave.

1           31.      The method of claim 29 wherein the releasable attachment is a  
2       bead of adhesive between said graft and said stent sheath and in which step (c) further  
3       comprises releasing said attachment by softening or dissolving said adhesive sufficiently  
4       via exposure to said intraluminal fluid to allow said graft to be pulled away from said  
5       stent sheath.

1           32.      The method of claim 29 wherein the stent sheath comprises a  
2       slot therein adapted to receive a portion of the graft and the pusher comprises an  
3       indented portion thereof, the releasable attachment comprising a portion of the graft  
4       disposed within the slot and pinched between the pusher and the stent sheath prior to  
5       and during introduction into the lumen, and in which step (c) further comprises  
6       releasing the attachment by moving the stent sheath relative to the pusher until the  
7       indented portion of the pusher aligns with the slot in the stent sheath and the portion of  
8       the graft disposed within the slot is no longer pinched between the pusher and the stent  
9       sheath.

1           33.      The method of claim 29 wherein the releasable attachment is a  
2       suture and in which step (c) further comprises releasing said suture by cutting the  
3       suture or untying a slip-knot in said suture.

1           34.      The method of claim 33 wherein the delivery system further

2 comprises a pusher underlying the stent sheath proximal to the stent, the pusher  
3 comprising an inner lumen axially therethrough and a cutter, a tip comprising a tip  
4 sheath overlying a distal end of the stent and attached to an inner core extending axially  
5 through the stent and through the pusher inner lumen, wherein step (c) comprises first  
6 moving the inner core distally relative to the stent sheath to release the stent distal end  
7 from the tip sheath and then moving said pusher relative to said stent sheath to cut said  
8 suture.

1               35. The method of claim 34 wherein the stent sheath has a  
2 circumference having therein a suture connection point and a set of radially opposite  
3 through-holes and the pusher has a distal end having therein a window distally adjacent  
4 the cutter, the method further comprising in step (a) radially aligning the pusher  
5 window with the stent sheath through-holes, and suturing the graft to the stent sheath  
6 by anchoring opposite ends of the suture through the suture connection point and  
7 threading an intermediate portion of the suture through the graft, the stent sheath  
8 through-holes, and the pusher window.

1               36. The method of claim 35 further comprising suturing the graft to  
2 the stent sheath by the steps of:

- 3               i) anchoring a first end of the suture at the suture connection point,
- 4               ii) extending the suture along the stent sheath;
- 5               iii) piercing the graft one or more times with the suture;
- 6               iv) extending the suture along the stent sheath;

7                         v)     entering the stent sheath radially through one of the through-  
8     holes, extending the suture through the pusher window, and exiting the stent sheath  
9     through the opposite through-hole;

10                         vi)    extending the suture along the stent sheath;

11                         vii)    piercing the graft one or more times with the suture;

12                         viii)   extending the suture semi-circumferentially around the sheath;

13     and

14                         ix)    anchoring a second end of the suture at the suture connection  
15     point or to the first end of the suture.

1                         37.    The method of claim 36 wherein the steps are carried out in  
2     sequential order from (i) to (ix), and steps (ii) and (vi) comprise extending the suture  
3     distally and step (iv) comprises extending the suture proximally.

1                         38.    The method of claim 36 wherein the steps are carried out in  
2     reverse sequential order from (ix) to (i), and steps (ii) and (vi) comprise extending the  
3     suture proximally and step (iv) comprises extending the suture distally.

1                         39.    The method of claim 24 further comprising the steps of:

2                         e)    preparing the delivery system for withdrawal, and

3                         f)    withdrawing the delivery system.

1                         40.    The method of claim 24 further comprising the steps of:

2                   e) preparing the delivery system for withdrawal by

3                   i) advancing the pusher into the tip sheath; and

4                   ii) advancing the stent sheath until a distal end of the stent

5                   sheath is adjacent to a proximal end of the tip sheath, and

6                   f) withdrawing the delivery system.

1                  41. The method of claim 27 wherein step (a) further comprises

2                  locking said stent sheath to said pusher, biasing said inner core under slight tension,

3                  and locking said inner core to said pusher; and wherein step (c) further comprises

4                  unlocking said inner core from said pusher prior to distally moving the inner core, and

5                  unlocking said stent sheath from said pusher prior to retracting said stent sheath.